

REMARKS

Formal Matters

In the specification, the paragraph describing the priority information has been amended to make it consistent with the filing information consistent with the PTO records. Specifically, the filing date for USSN 08/664,228 was described by Applicants to be June 6, 1996, but was reported by the PTO as June 7, 1996. The amendment to the description of Figure 2 corrects a typographical error. Support appears in Figure 6.

Claims 20-25, 27, 29 and 30 remain in this application. Claims 1-19, 26 and 28 and 31-73 have been canceled, and Claims 20-25 and 27 are amended. No new matter is added by the amendments.

Support for the amendments is found throughout the specification, at specifically at page 5, lines 15-16 and Figure 6.

In view of the Examiner's earlier restriction requirement, applicants retain the right to present withdrawn and cancelled subject matter (*e.g.*, claims 1-19, 26, 28 and 31-73) in subsequent prosecution.

The Rejection Under 35 U.S.C. § 101

Claims 20-30 are remain rejected under 35 U.S.C. § 101, allegedly because they are drawn to an invention with no apparent or disclosed specific, substantial and credible utility.

Specifically, the Examiner has asserted the following:

- (1) That no experimental evidence has been provided that agonist activation of the claimed protein induces inflammatory response;
- (2) The "specific and substantial" utility must be *in currently available form*, without the need for further research;
- (3) Applicants assertion that the PF4AR polypeptides of the invention are proinflammatory agents is not believable (*e.g.*, incredible) on its face. Specifically the record does not support a conclusion that any GPCR will have an effect on inflammation;

- (4) The declaration of James Lee is insufficient because it does not address the issue of additional experimentation required before realization of a practical application;
- (5) The application does not disclose the identity of a specific chemokine that regulates inflammation by acting upon the protein of the instant invention.

In response, Applicants respectfully traverse the rejection. Essentially, the Examiner is arguing that Applicants assertion of utility is incomplete or it has not been sufficiently perfected. Applicants respectfully disagree. With respect to point (1) and (4), experimental evidence of a specific and credible utility is not necessary. With respect to point (2), specifically the assertion of utility *in currently available form*, Applicants respectfully submit that no further experimentation is necessary in order appreciate that the claimed polypeptides are useful in the inflammatory cascade. The facts of this case are not analogous to those of *Brenner v. Manson*. In *Brenner*, the proponent argued that utility for the process was present by inference through a showing of utility for other structurally similar compounds. In short, the deficiency of *Brenner* was that there was no disclosed utility. Applicants have directly and unambiguously disclosed that the claimed polypeptides are proinflammatory. This assertion is corroborated with subsequent experimental findings of others as summarized in the Lee declaration submitted on April 14, 2006.

With respect to point (3), Applicants have not said, and do not intend to infer that *any* GPCR polypeptide is active in the immune cascade. In point of fact, Applicant said on page 13 of their prior April 14, 2006 response that the *subset* of GPCR polypeptides, specifically *PF4AR* polypeptides (also known as *IL-8R* polypeptides) are active in inflammation. It has since been corroborated and proven in the scientific literature that the polypeptides appearing in Figures 2, 4, 5 are active in the immune cascade.

With respect to point (5), the Examiner is essentially saying that Applicants must teach and disclose a ligand in order to establish a utility for the claimed receptor. Interestingly, the Examiner is essentially arguing that Applicants must not only teach a utility for the disclosed polypeptide, but also for those polypeptide which interact with it. If this were the standard,

carried to its logical extension, no novel molecules would be patentable unless there was also a disclosure of the binding partners.

In summary, Applicants have unequivocally and unambiguously asserted that the claimed polypeptides have utility in inflammation. While Applicants have not provided experimental evidence of this in the application as filed, such corroborative experimental evidence has been provided via declaration. The disclosure of the sequence of Figure 4 is specific and the assertion of its effect on inflammation is both specific and credible.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 20-30 under 35 U.S.C. § 101.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 20-30 are rejected under 35 U.S.C. § 112, First Paragraph, as allegedly failing to teach how to use the invention for reasons similar to those recited under 35 U.S.C. § 101.

In response, Applicants arguments responsive to the rejection under 35 U.S.C. § 101 are dispositive of this rejection as well.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 20-30 are rejected under 35 U.S.C. § 112, Second Paragraph, as allegedly being indefinite.

Specifically, the Examiner has asserted the following:

- (1) The limitation PF4AR is indefinite;
- (2) Claims 25 and 27 are vague and indefinite because of the text "extracellular segment";
- (3) Claims 26 and 28 are vague and indefinite because there is allegedly no antecedent basis for "the extracellular region".

In response, Applicants amendments render the rejection moot. In particular, Claims 26 and 28 have been cancelled, thereby eliminating the alleged confusion between the recited fragments on page 5, lines 17 and 18 of the homologous sequence of Figure 2, and the limitation of "at least 10 amino acid residues." As described textually on page 5, lines 15-16 and

graphically shown in Figure 6, there are 4 extracellular segments in Figure 2. Thus, the "extracellular segment" contemplated by claims 25 and 27 in Figure 5 are readily ascertainable by one of ordinary skill as the corresponding extracellular regions.

SUMMARY

Claims 20-25, 27, 29-30 are pending in the application. Claims 1-19, 26, 28 and 31-73 are canceled without prejudice to later prosecution.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is strongly encouraged to call the undersigned at the number indicated below.

This response/amendment is submitted with a petition for a 3-month extension of time and fees. If additional fees are required in this filing, applicants authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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